

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Respectfully,  
Howard J. Worman & Naoto Mamiya  
Washington, D.C. 20231  
BOX: PATENT APPLICATION  
S I R:

September 29, 1999

Transmitted herewith for filing are the specification and claims of the patent application of:

Howard J. Worman & Naoto Mamiya for  
Inventor(s)

HCY E2 PROTEIN BINDING AGENTS FOR TREATMENT OF HEPATITIS C VIRUS INFECTION  
Title of Invention

Also enclosed are:

☒ 8 sheet(s) of ☐ informal ☒ formal drawings.

☐ Oath or declaration of Applicant(s).

☐ A power of attorney

☐ An assignment of the invention to \_\_\_\_\_

☒ A Preliminary Amendment

☒ A verified statement to establish small entity status under 37 C.F.R. §1.9 and §1.27.

The filing fee is calculated as follows:

CLAIMS AS FILED, LESS ANY CLAIMS CANCELLED BY AMENDMENT

	NUMBER FILED		NUMBER EXTRA*		RATE		FEE		
					SMALL ENTITY	OTHER ENTITY		SMALL ENTITY	OTHER ENTITY
Total Claims	30 -20	=	10	X	\$ 9.00	\$18.00	=	\$ 90	\$
Independent Claims	3 -3	=	0	X	\$39.00	\$78.00	=	\$ 0	\$
Multiple Dependent Claims Presented:        ___ Yes <u>X</u> No					\$130.00	\$260.00	=	\$ 0	\$
*If the different in Col. 1 is 1 ss than zero, enter "0" in Col. 2					BASIC FEE			\$ 380	\$ 760
					TOTAL FEE			\$ 470	\$

Applicants: Howard J. Worman & Naoto Mamiya  
Serial No: Not Yet Known  
Filed: Herewith

Letter of Transmittal  
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X A check in the amount of \$470 to cover the filing fee.

\_\_\_\_ Please charge Deposit Account No. \_\_\_\_\_ in the amount of  
\$\_\_\_\_\_.

X The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the following or credit any over-payment to Account No. 03-3125:

X Filing fees under 37 C.F.R. §1.16.

X Patent application processing fees under 37 C.F.R. §1.17.


\_\_\_\_ The issue fee set in 37 C.F.R. §1.18 at or before mailing of the Notice of Allowance, pursuant to 37 C.F.R. §1.311(b).

X Three copies of this sheet are enclosed.

A certified copy of previously filed foreign application No. \_\_\_\_\_  
\_\_\_\_\_ filed in \_\_\_\_\_ on \_\_\_\_\_  
Applicant(s) hereby claim priority based upon this aforementioned  
foreign application under 35 U.S.C. §119.

X	Other (identify)	Express Mail Certificate of Mailing Bearing Label No. EL066381049US, dated September 29, 1999

Respectfully submitted,

  
John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

Applicant or Patentee: ward J. Worman et al. Attorney's JPW/GJG/YFL  
Serial or Patent No.: Not Yet Known Docket No: 0575/54805  
Filed or Issued: Herewith  
Title of Invention or Patent: HCV E2 PROTEIN BINDING AGENTS FOR TREATMENT OF  
HEPATITIS C VIRUS INFECTION

VERIFIED STATEMENT (DECLARATION) CLAIMING  
SMALL ENTITY STATUS UNDER 37 C.F.R. §1.9(f)  
AND §1.27(d) - NONPROFIT ORGANIZATION

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Organization: The Trustees of Columbia University in the City of New York

Address of Organization: 110 Low Memorial Library, West 116th Street & Broadway  
New York, NY 10027

TYPE OF ORGANIZATION:

☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION  
TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C. §§501(a) and  
501(c)(3)  
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED  
STATES OF AMERICA  
NAME OF STATE: \_\_\_\_\_  
CITATION OF STATUTE: \_\_\_\_\_  
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE 26 U.S.C.  
§§501(a) and 501(c)(3) IF LOCATED IN THE UNITED STATES OF AMERICA  
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE  
OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA  
NAME OF STATE: \_\_\_\_\_  
CITATION OF STATUTE: \_\_\_\_\_

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. §1.9(e)\* for purposes of paying reduced fees under 35 U.S.C. §41(a) and 41(b), with regard to the invention entitled  
HCV E2 PROTEIN BINDING AGENTS FOR TREATMENT OF HEPATITIS C VIRUS INFECTION

by inventor(s) Howard J. Worman et al.

described in:

☒ the specification filed herewith  
application serial no. \_\_\_\_\_ filed \_\_\_\_\_  
patent no. \_\_\_\_\_ issued \_\_\_\_\_

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive each individual, concern, or organization known to have rights to the invention is listed below<sup>a</sup> and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d)\* or a nonprofit organization under 37 C.F.R. 1.9(e)\*

<sup>a</sup> NOTE: Separate verified statements are required from each person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

Name: NONE

Address: \_\_\_\_\_

37 C.F.R. §§1.9(d), 1.9(e)

(d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published on September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:

§121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.

(a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

(b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.

(e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

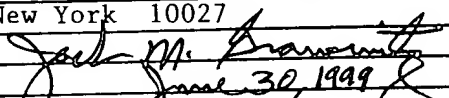
SCANNED 4

Applicants: Howard J Worman et al.  
Serial No.: Not Yet      own  
Filed: Herewith

Small Entity/Nonprofit  
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Mr. Jack M. Granowitz  
Title In Organization: Executive Director, Columbia Innovation Enterprise  
Address: Engineering Terrace - Suite 363, Amsterdam and 120th Street  
New York, New York 10027  
Signature:   
Date Of Signature: June 30, 1999

37 C.F.R. §1.28(b)

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to §1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to §1.34(a) of this part.

SCANNED 4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Howard J. Worman and Naoto Mamiya  
U.S. Ser. No. : Not Yet Known  
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1185 Avenue of the Americas  
New York, New York 10036  
September 29, 1999

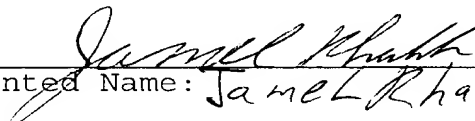
Assistant Commissioner for Patents  
Washington, D.C. 20231  
BOX: PATENT APPLICATION

SIR:

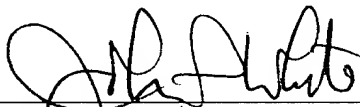
**EXPRESS MAIL CERTIFICATE OF MAILING  
FOR ABOVE-IDENTIFIED APPLICATION**

"Express Mail" mailing label number: EL 066 381 049 US  
Date of Deposit: September 29, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Printed Name: Jamel Rhabb

Respectfully submitted,

  
John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400